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THE SYNTHETIC ORGANIC CHEMICAL MANUFACTURERS ASSOCIATION

COMMENTS

on

EPA'S PROPOSED RULE ON CROSS-MEDIA ELECTRONIC REPORTING AND RECORDKEEPING ("CROMERRR")

66 FED. REG. 46162 (AUG. 31, 2001)

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EXECUTIVE SUMMARY

The Synthetic Organic Chemical Manufacturers Association ("SOCMA") appreciates the opportunity to submit these comments on EPA's proposed rule relating to Cross-Media Electronic Reporting and Recordkeeping ("CROMERRR"). Although couched as voluntary, as drafted the proposed rule actually would impose mandatory, extensive and infeasible requirements on virtually every environmental record at virtually every facility subject to environmental regulation. EPA has significantly overestimated the need for, and benefits of, the proposed rule, while significantly underestimating its burdens.

As discussed in these comments, the scope of CROMERRR's proposed recordkeeping requirements defies rationality. As drafted, CROMERRR would apply to every environmental record, if ever on a computer at any point during its life cycle. To avoid CROMERRR, apparently no computers could be used to create, modify, store, or distribute the data. And any use of computers would require prior EPA approval. Even then, the adaptation of computer systems to meet CROMERRR's proposed requirements would be difficult, expensive, and in many cases infeasible. Notwithstanding that computers are ubiquitous and are essential to the efficient operation of every business, CROMERRR in essence would require a return to the era of pencil, paper, and calculators.

These issues are not merely academic. If implemented in its current form, CROMERRR could well become the most costly of EPA's regulations, with costs in the billions of dollars. In the face of these costs, SOCMA is particularly concerned that EPA's process for developing the proposed rule failed to follow the Small Business

Regulatory Enforcement and Fairness Act ("SBREFA") and the Regulatory Flexibility Act. Consequently, there was no hearing for the significant financial impacts that would be imposed on small businesses.

It is apparent that, when drafting the proposed rule, EPA did not foresee its impacts. The many and substantial costs -- direct and indirect -- of the proposed rule far outweigh the benefits. CROMERRR's proposed recordkeeping requirements are not necessary to comply with the Government Paperwork Elimination Act or to allow companies to generate, manage and retain information in electronic format. For the reasons discussed in these comments, the recordkeeping portion of the proposed rule should be withdrawn.

I. INTRODUCTION

SOCMA is a trade association representing batch and custom chemical manufacturers, a highly innovative, entrepreneurial and customer-driven sector of the chemical industry. More than 2,000 batch processing facilities produce 50,000 of the specialty and custom chemicals manufactured in the U.S. at a value about $60 billion annually. SOCMA members are representative of these facilities, which are typically small businesses with fewer than 50 employees and less than $100 million in annual sales.

SOCMA supports EPA's efforts to add efficiency to reporting and recordkeeping. Minimizing costs of information management is essential if SOCMA's members are to maintain their competitiveness. As proposed, however, CROMERRR's recordkeeping requirements -- the focus of these comments -- would impose massive,

mandatory costs, to the extent that they could be implemented at all. And yet the proposal was developed without considering these costs and without assessing CROMERRR's impact on small businesses. Accordingly, for the reasons explained in these comments, the recordkeeping provisions of CROMERRR should be withdrawn.

II. VIRTUALLY ALL ENVIRONMENTAL RECORDS AT VIRTUALLY ALL FACILITIES ARE ELECTRONIC

Electronic recordkeeping is pervasive. Virtually all EPA-regulated facilities are subject to recordkeeping requirements, and virtually all such information passes through a computer at some point in its life cycle. This is the case across all EPA programs (air, water, waste, release reporting, TSCA, etc.) Exhibit 1 to these comments presents a partial list of the various EPA programs and the types of information that typically involve electronic recordkeeping.

Many different kinds of electronic recordkeeping systems are in place, for many different purposes. In some cases, the electronic record simply is a word processing document or spreadsheet. In other cases, highly automated data systems collect environmental data as an initial matter, manage it, transform it into a usable form, store it, and sometimes transmit it directly to EPA. As a practical matter, electronic recordkeeping is not voluntary and cannot be foregone. Companies and facilities cannot possibly manage and retain the information they are required to, for both business and environmental compliance purposes, by returning to the pre-computer age.

III. AS DRAFTED, CROMERRR WOULD NOT BE VOLUNTARY, BUT INSTEAD WOULD APPLY TO ALL ENVIRONMENTAL RECORDKEEPING

The preamble to CROMERRR asserts that electronic recordkeeping would be voluntary:

- "Under today's proposal, electronic document submission or electronic recordkeeping will be totally voluntary."[1]
- "Today's rule is not subject to the RFA [Regulatory Flexibility Act] because electronic reporting and recordkeeping is voluntary . . . ."[2]
- "However, it was also assumed that a very low number of facilities (0.5 percent) of the current regulated entities, would elect to acquire new electronic recordkeeping systems to implement the CROMERRR recordkeeping option."[3]

This underpinning of CROMERRR – on which both the substantive requirements and the EPA's economic analysis are based – is flawed. In fact, the proposed requirements would be mandatory. CROMERRR would apply to all "records that EPA or authorized State, tribal or local programs require regulated entities to maintain under any of the environmental programs governed by Title 40 of the CFR or related State, tribal and local laws and regulations."[4] "Electronic record" would be defined expansively as "any combination of text, graphics, data, audio, pictorial, or other information represented in digital form that is created, modified, maintained, archived, retrieved or distributed by a computer system."[5]

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[1] 66 Fed. Reg. at 46162.

[2] 66 Fed. Reg. at 46186.

[3] 66 Fed. Reg. at 46178.

[4] 66 Fed. Reg. at 46168.

[5] 66 Fed. Reg. at 46189.

Qualifying as an "electronic record" means that information kept electronically to meet an EPA recordkeeping requirement would be subject to the extensive array of requirements in Subpart C of proposed Part 3. Proposed § 3.100(a) would provide in part:

> An electronic record . . . will satisfy a recordkeeping requirement of an EPA-administered environmental program under this Title [i.e., 40 CFR] only if it is generated and maintained by an acceptable electronic record-retention system as specified under this subsection.[6]

As discussed below, the requirements for an "acceptable record-retention system" would entail substantial costs and in many cases would be infeasible.

Accordingly, CROMERRR's expansive requirements apparently would apply to any information ever passing through a computer system at any point during its life cycle. Even word processing documents and spreadsheets would be covered. Printing and filing a hard copy would not exclude the information from CROMERRR, because the data at least at some point would have been created or modified or maintained or archived by a computer system and therefore would qualify as a CROMERRR "electronic record." In today's electronic age, businesses by necessity have to collect and store data on a computer, and so CROMERRR would not really be "voluntary" at all.

The fundamental error underlying the proposal is that it is written as if all extant records currently are paper records. CROMERRR would establish that use of a computer to meet EPA recordkeeping requirements is now impermissible, and would remain so unless and until EPA makes a future announcement permitting such practices.

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[6] 66 Fed. Reg. at 46190 (emphasis added).

The CROMERRR preamble states that EPA will specifically inform regulated entities when they may begin to keep mandated records on a computer:

> Any regulated company or other entity that maintains records addressed by today's proposal . . . under EPA regulations can store them in an electronic form subject to the proposed criteria for electronic recordkeeping as soon as EPA announces that the specified records may be kept electronically.[7]

While EPA may not have intended this result, the words used in the preamble would appear to make all current electronic recordkeeping unacceptable for meeting EPA recordkeeping requirements.

In sum, the fundamental flaw in the proposal is EPA's misunderstanding of the role of electronic recordkeeping. EPA assumed that there was little or none, when in fact electronic recordkeeping is indispensable and pervasive. Regulated entities cannot choose to forego it.

IV. THE PROPOSED REQUIREMENTS FOR ELECTRONIC RECORDS WOULD BE TECHNICALLY AND ECONOMICALLY INFEASIBLE

CROMERRR would significantly impact electronic data collection and recordkeeping systems. In many cases, the hardware and software demands imposed by CROMERRR would be technologically infeasible, or at a minimum very challenging. Even where feasible, the economic impacts of CROMERRR could make it the most costly of EPA regulations.

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[7] 66 Fed. Reg. at 46167 (emphasis added).

A. Technological Issues

The proposed rule would establish very specific, expensive computer system and software requirements for electronic records to be in an "acceptable record retention system." Among the proposed CROMERRR's myriad requirements, such acceptable record retention systems would have to:[8]

- Generate and maintain accurate and complete electronic records in a form that may not be altered without detection. This level of security is not readily available in commercial software. Systems security instead focuses on enabling access only to authorized persons.
- Maintain all electronic records without alteration for the entirety of the required period for record retention. Many EPA recordkeeping requirements have lengthy retention periods. For example, TSCA Section 8(c) allegations must be retained for 5 to 30 years, depending on the nature of the allegation.[9] The record retention period for the FIFRA Good Laboratory Practice regulations is for the life of the pesticide registration, which could be decades.[10] Given the changes in both software and hardware that will occur over time, maintaining legacy systems or transitioning the data accurately across multiple generations of computer systems is very difficult.

[8] Compare 21 CFR Part 11, Subpart B with proposed 40 CFR Part 3, Subpart C, 66 Fed. Reg. at 46190.

[9] 40 C.F.R. § 717.15

[10] 40 C.F.R. § 160.195(b)(1).

- Produce accurate and complete copies of any electronic record and render these available, in both human readable and electronic form, for on-site inspection and off-site review, for the entirety of the record retention period. This means that EPA would be authorized to access a regulated entity's computer system and search it. Although EPA should have a reasonable right of access to the extent necessary to ascertain compliance, EPA should not have unfettered access to computer systems, which will contain highly sensitive and confidential business information. Designing firewalls to provide the appropriate degree of access would be difficult and expensive.

- Use secure, computer-generated, time-stamped audit trails that automatically record the date and time of operator entries and actions that create, modify, or delete electronic records. Many computer systems and software lack this capability. For example, even basis software such as Microsoft Excel® lacks an audit trail capability, and apparently could not be used without an expensive (and potentially problematic) add-on feature.[11] Custom software often used for management of environmental data typically does not have this capability, and rewriting the software and retooling the systems to provide the capability would be difficult, time-consuming and expensive.

[11] See, e.g., www.fda.gov/ohrms/dockets/dockets/00d1543/mm0001_01.htm (alternatively, see entry for 3/23/01 at www.fda.gov/ohrms/dockets/dockets/00d1541/00d1541.htm) (report of vendor presentation to FDA of proprietary software purportedly able to add an audit trail feature to Excel); fuller description at www.wimmersystems.com.

- Ensure that record changes do not obscure previously recorded information and that audit trail information is retained for at least the record retention period to be available for agency review. This tack-on to the audit trail requirement, like many other components of CROMERRR, would pose major hardware challenges, including the need to vastly expand computer memory.
- Archive electronic records in an electronic format which preserves the context, meta data, and audit trail. If necessary, ensure that complete records can be transferred to a new system including related meta data.

These are very challenging requirements. They are beyond the state of current off-the-shelf software. In many cases involving interfaces among different electronic systems, the CROMERRR requirements are not technically feasible. Given the myriad of systems, modifications of hardware and software to meet the CROMERRR criteria would be a practical impossibility.

B. Economic Issues

CROMERRR also would be economically infeasible. In projecting that the proposal would impact only 428 facilities, with total startup costs of about $10MM and annual O&M costs of about $5MM, based on per-facility costs of about $40,000,[12] EPA failed to properly assess the scope of the proposal. EPA assumed that, because CROMERRR would be "voluntary," few facilities would take advantage of electronic reporting and recordkeeping, and the costs would be low.

[12] 66 Fed. Reg. at 46178.

In fact, having debunked the myth that CROMERRR would be voluntary, it becomes apparent that the proposal would apply to virtually every EPA-regulated facility. At a minimum, CROMERRR would reach at least the 1.2 million entities filing reports under EPA regulations. The actual figure might be higher – industry estimates that up to three to five million facilities may be subject to EPA regulation. Virtually every such facility will use some sort of computer system for its records.

In projecting per-facility costs of only $40,000, EPA again presumed that the requirements would be voluntary and that each affected facility would subject only a few of its records to CROMERRR. Instead, virtually every environmental record would pass through a computer at some point during its life cycle and thus would be an "electronic record." As evidenced by the comparable FDA experience, CROMERRR's implementation costs would make the regulation one of EPA's most expensive regulations. The FDA rule reportedly is costing some pharmaceutical companies over $100 million to implement.

Even applying EPA's lowball per-facility cost estimate to the minimum number of affected facilities, however, shows that the proposal would cost well over $40 billion. What are the benefits that would justify such an unprecedented expenditure?

V. BECAUSE THE AGENCY ERRONEOUSLY CALCULATED THE BURDENS ASSOCIATED WITH CROMERRR, IT HAS FAILED TO COMPLY WITH THE RFA, SBREFA AND E.O. 12866

CROMERRR is a "significant" proposed rule under Executive Order 12866 – as it would have an impact on the economy of $100 million or more – and it would trigger the Regulatory Flexibility Act and the Small Business Regulatory

Enforcement Act ("SBREFA").[13] Yet EPA failed to comply with these authorities, again relying on the untenable position that CROMERRR would be voluntary. As the majority of SOCMA's members are small businesses, SOCMA is particularly concerned that EPA failed to properly evaluate the disproportionate impacts of CROMERRR on small businesses.

A. CROMERRR Would Have Disproportionate Impact On Small Batch Chemical Manufacturers

Because of their unique operations, the burdens associated with CROMERRR would be particularly acute for the batch and specialty sectors of the U.S. chemical industry. The majority of SOCMA members produce what are known as specialty chemicals. Specialty chemicals are a category of chemicals that are specially formulated to meet detailed specifications. Specialty chemicals usually have unique, special purposes, such as to make nylon fibers stronger, or to make an active ingredient in medicine. Specialty chemicals are often essential ingredients in the manufacture of another product. Making these products is an ever-changing business, often requiring small quantities in a timely manner. The specialized nature of SOCMA's members' products thus often calls for batch manufacturing operations.

Batch processing provides an efficient and frequently the only method to make small quantities of chemicals to meet specific needs and consumer demands for specialized products. Batch processors must be able to respond quickly to new requirements by customers, fill small market niches and develop new products. They are at the cutting edge of new technology, provide products often made nowhere else in the

[13] The RFA, as amended by SBREFA, is codified at 5 U.S.C. §§ 601-612 (2000). The specific provisions of the SBREFA amendments can be found at Title II, Pub. L. No. 104-121.

world and help keep imports down by responding quickly to customer demands for service and delivery. This segment of the chemical industry retains a high degree of entrepreneurship and must retain the flexibility to meet ever-changing needs and new technological developments.

Batch processes are distinct from continuous operations in that a continuous operation has a constant raw material feed to each unit operation and continual product withdrawal from each unit operation. A batch process has an intermittent introduction of frequently changing raw materials into the process, varying process conditions imposed on the process within the same vessel. Products are manufactured in separate, distinct "batches," by operations that start and finish within relatively shorter periods of time. Because the products and the processes change, the process operating conditions and even the configuration of the equipment can change as well. A single piece of equipment can be put to multiple uses and may well contain a range of different materials over the course of a year. In fact, a SOCMA study found that one member company produced a total of 566 different products over a seven-year period at one facility.

As a result of their frequent variations and changes in product lines, and the unique aspects of batch processing, specialty chemical manufacturers would be disproportionately impacted by the recordkeeping provisions of CROMERRR. Unlike the burdens imposed on facilities with static product lines, the burdens likely to be imposed on batch manufacturers would increase exponentially as the number of chemicals produced increases. This increase in chemical products manufactured leads to increased environmental monitoring, recordkeeping and reporting obligations vis-à-vis

EPA regulations. As noted previously, use of computers to monitor, and compile environmental information, as well as developing environmental reports is ubiquitous. The frequent changes in equipment configurations would lead to particularly significant hardware and software challenges in meeting CROMERRR's recordkeeping requirements. Computers also are typically used for such activities as maintaining inventories of both raw materials and products, purchasing records, labeling documents and shipping documents, all of which are more complex and extensive for specialty chemical manufacturers.

Compounding this burden, and creating a further disparity compared to impacts imposed on continuous operations, is the fact that many batch and specialty chemical producers are small businesses. Nearly 75% of SOCMA's active membership meets the definition of small business used by the Small Business Administration. Accordingly, SOCMA is particularly concerned with EPA's failure to address small business concerns in the rulemaking process.

B. CROMERRR Impermissibly Ignores SBREFA

SBREFA was intended to provide an opportunity for small businesses likely to be impacted by an upcoming regulatory proposal to raise concerns and suggestions early in the regulatory process. A significant component of SBREFA establishes additional administrative procedures during the rulemaking process specific to EPA and the Occupational Safety and Health Administration ("OSHA"). In considering the impact of a rule on small businesses, SBREFA requires EPA to seek input from representatives from potentially impacted small entities prior to publication of the

proposed rule. In order to avoid this outreach, EPA must certify that the proposed rule will not have a "significant impact on a substantial number of small companies" in accordance with the Regulatory Flexibility Act, 5 U.S.C. § 603. EPA must provide a factual basis to accompany such a determination.

In light of the aforementioned shortcomings in accurately assessing the economic impacts of CROMERRR's recordkeeping provisions, EPA lacks the factual basis required to justify its certification of no small business impact. It is now clear that many small businesses will be impacted if the proposed rule is promulgated in its current form. In order to comply with SBREFA, EPA must withdraw the current proposal. Thereafter, before proceeding with a new proposal, EPA would have to conduct extensive small business outreach, convene appropriate small entity review panels, develop a realistic economic impact assessment, and fully consider regulatory alternatives to minimize impacts on small entities.

C. CROMERRR Would Fail Under Other Authorities Calling for Reduced Regulatory Burdens

The proposal also is inconsistent with Executive Order 12866 and with other agency-wide initiatives on reducing regulatory burdens. Recent initiatives to reform the rulemaking process require a review of (and some balance between) the costs of a regulation and its benefits, and a focus on regulations posing true risk. As former President Clinton stated, "[t]he American people deserve a regulatory system that works for them, not against them; a regulatory system that protects and improves their health, safety, environment, and well-being and improves the performance of the economy without imposing unacceptable or unreasonable costs on society . . . ." 58 Fed. Reg.

51735, 51736 (Oct. 4, 1993). Executive Order 12866 requires that each agency: "design its regulations in the most cost-effective manner to achieve the regulatory objective"; "identify and assess alternative forms of regulation"; and "propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs." 58 Fed. Reg. at 51735-36. These authorities also require EPA to evaluate possible alternatives to the proposed regulation.

This proposal is the type that Executive Order 12866 and the new Administration's regulatory initiatives are designed to prevent – one which imposes dramatically increased reporting and recordkeeping burdens to achieve no quantifiable benefits, and one where EPA has not adequately considered alternatives. Proceeding to a final regulation would be wholly inconsistent with the Administration's policies and initiatives.

VI. THE PROPOSED RECORDKEEPING REQUIREMENTS ARE NOT NEEDED TO SATISFY THE GOVERNMENT PAPERWORK ELIMINATION ACT

CROMERRR is EPA's response to the Government Paperwork Elimination Act ("GPEA").[14] The GPEA is an enabling statute, designed to facilitate (not discourage) electronic reporting and recordkeeping. Rather than implementing the GPEA, however, CROMERRR instead would frustrate the GPEA's mandate.

The GPEA has two provisions relating to recordkeeping. First, Section 1704(1) of the GPEA states that "agencies [shall] provide . . . for the option of the electronic maintenance, submission, or disclosure of information, when practicable as a substitute for paper." EPA has not identified any extant obstacles to electronic

[14] Pub. L. No. 105-277, Title XVII (Oct. 21, 1998).

maintenance of information. In fact, as noted in Section II of these comments, electronic recordkeeping is the primary mode of recordkeeping. Second, Section 1707 states that "[e]lectronic records submitted or maintained in accordance with procedures developed under this title, or electronic signatures or other forms of electronic authentication used in accordance with such procedures, shall not be denied legal effect, validity or enforceability because such records are in electronic form" No current EPA regulations preclude electronic recordkeeping. If EPA felt it necessary to take any action relating to recordkeeping under the GPEA, EPA need only promulgate simple language confirming that any requirement for maintaining a record may be satisfied by an electronic record, in lieu of a paper record.

CONCLUSION

For the reasons presented in these comments, SOCMA opposes the proposed recordkeeping requirements of CROMERRR as over-inclusive, impossibly burdensome, and inconsistent with the GPEA and EPA's other statutory authorities. The entire underpinning of the proposed recordkeeping requirements – the assumption that records are not maintained electronically at present – is flawed. CROMERRR would be mandatory, not voluntary, and it would apply across the board. Because the underlying flaws in CROMERRR as drafted are so fundamental, it cannot be repaired by minor adjustments. Instead, the proposed recordkeeping component of CROMERRR should be withdrawn.

As EPA considers its next steps following the close of the current period for comment, it should take full account of the wealth of information presented at the

several public meetings on CROMERRR. As noted at those meetings, EPA should not proceed with the preconception that any action is necessary to implement the GPEA. The status quo may be fine, as EPA regulations generally do not discriminate against electronic recordkeeping, and EPA program offices have at least implicitly recognized that electronic records may be comparable (or in fact preferable) to paper. To the extent that any regulation is necessary, SOCMA believes that it could be very simple and genuinely voluntary, such that its impact on small business and the rest of the regulated community is truly beneficial, rather than devastating. SOCMA looks forward to participating in a continuing dialogue with EPA.

For further information regarding these comments, please contact Mike Heyl, Senior Manager, Synthetic Organic Chemical Manufacturers Association, 1850 M Street, N.W., Suite 700, Washington, D.C. 20036, (202) 721-4100.

SYNTHETIC ORGANIC CHEMICAL MANUFACTURERS ASSOCIATION

Exhibit 1

Proposed CROMERRR Rule
Examples of Electronic Environmental Records Currently Maintained

The purpose of this document is to demonstrate the far-reaching implications of the recordkeeping provisions in the proposed CROMERRR rule as they pertain to existing EPA regulations for a typical chemical manufacturing facility. The following information, among others, commonly is generated or maintained electronically.

Process Monitoring Data – generated on the plant's Distributed Control System, and transferred to other systems for consolidation, data storage and reporting

- Air permits – continuous operating data (e.g., temperature, flow, pressure drop, etc.)
- NSPS regulations – air emission data from Continuous Emissions Monitoring Systems (CEMS)
- MACT regulations
- Water permits – discharge data (e.g., temperature, pH, flow, specific conductance, etc.)
- Injection well permits – injection data (e.g., injection flow and pressure, annulus pressure, etc.)
- RCRA – operating data (e.g., incinerator temperature, flow and pressure drop across scrubbers and carbon beds, etc.)

Raw Materials / Product (Purchase, Production, Inventories) – SAP or purchasing / cost accounting system

- EPCRA – TRI and Tier II reports (these are already submitted electronically)
- TSCA – import/export, Inventory Update Rule, Pre-manufacture Notifications
- RCRA – waste minimization

Lab Analyses

- Water permits – discharge characteristics
- RCRA – waste profiling/characterization
- RCRA / CERCLA – groundwater monitoring data
- Air permits – air emissions testing
- NSPS – CEMS quality assurance testing

Training Records – includes training material (both instructor-led and computer-based) and records of personnel receiving the training

- RCRA
- SPCC
- Storm Water Pollution Prevention Plan (SWP3)
- General environmental compliance

Preventive Maintenance and Repairs – includes both stand-alone PM systems and SAP systems

- Air permits and regulations – LDAR, emission control, etc.
- RCRA regulations and permits – Tanks, Subpart BB, CC
- Water permits

Data Generated Manually, but Converted into Electronic Records

- Air permits – visual observation log sheets
- Water permits – laboratory analytical results
- RCRA / SPCC – inspection checklists
- RCRA – waste manifests
- UIC – well workovers

Data Generated on "non-integrated" electronic devices

- Water permits – laboratory analytical results
- LDAR – leak testing

Regulatory Documents

- Regulatory "Plans" – SPCC, RMP, SWP3, Oil Spill Response
- Reports to EPA/State agencies
- Permit applications / supporting calculations
- Agency correspondence

Environmental Management System Components

- Data management systems / databases
- Guidance documents / operating procedures
- Self-auditing results
- Internal reports
- Intranet web pages

Facility / Equipment Design Information

- NSPS – equipment design details
- RCRA / CERCLA – monitoring well design
- UIC – injection well design